

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE



Application Number: 10/633,842  
Priority Docket No.: ZQI-127US  
Applicant: Rosiello, K.  
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TC/A.U.: 1723  
Examiner: Sorkin, David L.

Customer Number: 48329  
Confirmation No.: 5671

Commissioner of Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**DECLARATION UNDER 37 C.F.R. §1.132  
OF MR. KEITH ROSIELLO**

Dear Sir:

I, Keith M. Rosiello, hereby declare that:

1. I am currently the Vice President of Operations for Zymequest, Inc., the assignee of the above referenced application. I am an engineer by training. A copy of my current *curriculum vitae* is attached.
2. In my capacity as Vice President of Operations for Zymequest Inc., my job responsibilities include overseeing the research and development efforts of the company, and coordination of the company's efforts to secure intellectual property protection for its various inventions.
3. I am also the inventor of the instant application (U.S.S.N. 10/633,842). As the inventor, and as the company representative charged with overseeing the patenting process for company technologies, I am familiar with U.S.S.N. 10/633,842 and the invention disclosed and claimed therein.
4. I am also responsible for the international and the United States prosecution of WO 01/30505 ("the '505 application"), as well as WO 02/28451 ("the '451 application"), both of which are assigned in their entirety to Zymequest, Inc.

5. I am familiar with the '505 application, and the '451 application, and I am responsible for the company research and development efforts that involve the subject matter disclosed and claimed therein, and am responsible for overseeing the patenting of these technologies.
6. In addition, I am an inventor of the subject matter disclosed and claimed in the '505 application.
7. I am familiar with the requirements of 35 U.S.C. §102(b), and I understand that the '505 application and the '451 application are being cited as prior art against the instant application, such that the current claims are deemed by the USPTO to be anticipated by the '505 application and the '451 application.
8. I have reviewed the office action dated November 22, 2005. Based on my knowledge of the subject matter of the '505 application, I disagree with the Office's characterization that the '505 application discloses the subject matter claimed in the instant application.
9. The '505 application discloses and claims a flexible centrifuge bag, or "chamber". The bag is capable of expansion and contraction since it is fabricated from a flexible material. The walls of the bag, *i.e.*, the first side and second side, are directly attached to each other at their circumference.
10. In contrast, the centrifuge chamber claimed in the instant application is markedly different, in that it comprises axially expandible, annular flexible folds. In the instant application, the expandable wall of the chamber includes at least one pair of corresponding connected partitions. A first partition of the pair of partitions includes a first circumferential end attached to the circumference of the first side of the flexible chamber. A second partition of the pair of partitions includes a second circumferential end attached to the circumference of the second side of the flexible chamber. The walls of the chamber are not directly attached to each other at their circumference, as in the '505 application, but instead are attached to the partition at their circumference. This structure resembles an accordion, or bellows, and allows the chamber to expand in a

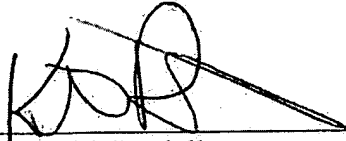
manner that substantially increases its volume as compared to the bag disclosed in the '505 application. This accordion-like feature is not disclosed in the '505 application.

11. FIGs 1, 3 and 4 in the '505 application do not illustrate the accordion-like structure described above. FIGs 1, 3, and 4 illustrate a bag set, that is, six non-partitioned centrifuge bags mounted on a rotor. This is described in at least page 3 line 25 of the '505 application, which refers to the invention as a "bag set". As a person skilled in the relevant art, I would not interpret FIGs 1, 3, or 4, in view of the specification, to reflect an accordion-like chamber. The bag set would not be interpreted as a single bag having the accordion-like structure disclosed and claimed in the instant application.
12. The single chamber having the expandable, accordion-like structure was not known or developed at the time of filing of the '505 application.
13. Regarding the '451 application, as stated above, I am an inventor of the subject matter disclosed and claimed therein. I note that the '451 application is a continuation in part of the '505 application.
14. I have reviewed the office action dated November 22, 2005. Based on my knowledge of the subject matter of the '451 application, I disagree that the '451 application discloses the subject matter claimed in the instant application.
15. The '451 application discloses and claims the same flexible centrifuge chamber, that is disclosed in the '505 application. The walls of the bag are directly attached to each other at their circumference. The improvements in the '451 application are not directed to the flexible chamber, but rather the fluid exchange systems, hubs, and methods for fluid exchange during continuous operation of the centrifuge.
16. In contrast to the '451 application, the centrifuge chamber claimed in the instant application is markedly different, in that it comprises axially expansible, annular flexible folds. In the instant application, the expandable wall of the chamber includes at least one pair of corresponding connected partitions. A first partition of the pair of partitions includes a first circumferential end attached to the circumference of the first side of the flexible chamber. A second partition of the pair of partitions includes a second

circumferential end attached to the circumference of the second side of the flexible chamber. The walls of the chamber are not directly attached to each other at their circumference, as in the '451 application, but instead are attached to the partition at their circumference. This structure resembles an accordion, or bellows, and allows the chamber to expand in a manner that substantially increases its volume as compared to the bag disclosed in the '451 application. This accordion-like feature of the chamber is not disclosed in the '451 application.

17. FIGs 3 and 7 in the '451 application do not illustrate the accordion-like structure described above. FIGs 3 and 7 illustrate the same chamber that is disclosed in the '505 application, in which the walls of the bag, *i.e.*, the first side and second side, are directly attached to each other at their circumference. In the cut away view illustrated by these figures, the center lines do not illustrate partitions, but rather the joining of the left and right bag sides at the circumference of the bag. As a person skilled in the relevant art, I would not interpret FIGs 3 or 7 in view of the specification, to reflect an accordion-like chamber.
18. The single chamber having the expandable, accordion-like structure was not known or developed at the time of filing of the '451 application.
19. Regarding U.S. Patent 2,686,006 to Hasselquist ("the '006 patent"), I have reviewed the '006 patent and am familiar with the disclosure. I have also reviewed the office action dated November 22, 2005, and its characterization of the '006 patent. Based on my knowledge of the subject matter of the '006 patent, I disagree that the '006 patent discloses the subject matter claimed in the instant application.
20. The '006 patent discloses and claims a bellows pump. The structure disclosed and illustrated therein, does not possess an axial opening through both sides of the bellows. In fact, the bellow pump would be rendered non-operational were it to have an axial openings on both sides, since it would not be able to compress air internal to the bellows—it would escape out the sides.

21. I declare further that all statements made in this Declaration of my own knowledge are true, that all statements made on information and belief are believed to be true, and further, that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of any patent that may issue from the present application.



Mr. Keith Rosiello  
Vice President of Operations  
Zymequest, Inc.

May 19, 2006  
Date: